



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/837,539 | 04/18/2001 | John M. Barker | 1032-P02148US1 | 7584 |

110 7590 11/25/2003

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

MARMOR II, CHARLES ALAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3736

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,539

Applicant(s)

BARKER ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Response to Office Action filed June 6, 2003. The Examiner acknowledges the proposed drawings corrections and the amendments to claims 1, 2, 5 and 8. Claims 1, 2, 5 and 8-20 are pending.

Drawings

2. The proposed drawings corrections filed June 6, 2003 are approved by the Examiner. New formal drawings including the approved drawing corrections are required in response to this Office Action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 2, 5 and 8-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Prestidge et al. (WO 00/20058). Prestidge et al. teach a safety needle apparatus. The apparatus is a medical device including a hollow housing **12**; a needle **20** having a sharpened tip **22** projecting forwardly from the housing; a spring biasing element **26** biasing the needle rearwardly; a needle retainer **30** releasably retaining the needle against the rearward bias of the

Art Unit: 3736

biasing element; and a flexible shield **18** fixedly attached to the housing, projecting forwardly from the housing. The shield is configured for insertion into a patient. The shield sheathes the needle such that in a projecting position the sharpened tip of the needle projects beyond the forward edge of the shield, and in a retracted position the sharpened tip is enclosed within the shield. The shield is substantially puncture resistant so that the axial force required to buckle the shield is less than the force necessary to puncture the shield with the needle in order to prevent inadvertent contact with the contaminated needle. A connector **14** in fluid communication with the needle for attaching to a fluid device and a stop **25** for limiting the displacement of the needle are also provided. A lock that locks the needle in the retracted position is formed by the proximal end of the retainer **30** as illustrated in Figures 2 and 4.

In operation, the needle is inserted into the patient; the actuator **124,154** of the needle retainer is actuated such that the biasing element displaces the needle so the needle is locked in a shielded position; and fluid is infused or blood is collected through the shielded needle by the fluid device connected to connector **104**.

Response to Arguments

5. Applicant's arguments filed June 6, 2003 regarding the claim objections and the rejections under 35 USC 112, second paragraph, have been considered and are persuasive. As such, said claim objections and the rejections under 35 USC 112, second paragraph, have been withdrawn.

Applicant's arguments filed June 6, 2003 regarding the rejections under nonstatutory, obviousness-type double patenting have been considered and are persuasive. As such, said

Art Unit: 3736

double patenting rejections have been withdrawn in view of the Terminal Disclaimer filed June 6, 2003.


Applicant's arguments with respect to the rejection of claims 1, 2, 5 and 8-20 under 35 USC 102(b) have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Yoon ('053) does not teach or suggest a biasing element that biases the needle rearwardly; a needle retainer that retains the needle against the bias of the biasing element; a flexible shield fixedly attached to the housing; and retracting a needle rearwardly into a shield. These arguments are moot in view of the new grounds of rejection citing Prestidge et al. as set forth hereinabove.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
November 19, 2003